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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,011	02/26/2002	J. P. Bourguignon	37522-1001C2	3397

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EXAMINER	
BORIN, MICHAEL L	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,011	BOURGUIGNON, J. P.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-14 and 23-33* is/are pending in the application.

4a) Of the above claim(s) *2-13,24 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,23,25-27 and 29-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Amendment filed 06/01/2006 is acknowledged. Claims 30-33 are added. Claims 2-14, 23-33 are pending. Claim 14 is amended to return to the version directed to "influencing glutamate receptor-controlled cells". Claims 2-13, 24,28 remain withdrawn from consideration. Claims 14,23,25-27,29-33 are under consideration.

2. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Objections

3. Claim 31 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 25. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 U.S.C. § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 14,23,25-27,29-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are rendered vague and indefinite by the language "method for influencing" used in claims 14-17, 20. "Influence" is a relative term, it is not defined by the claim, the specification does not provide a standard for ascertaining the requisite effect to constitute "influence", and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear whether "influence" constitutes effect on receptor activity (inhibition or augmentation?), or effect on binding to the receptor, or effect on receptor internalization, etc.

The amendment "in the amount sufficient to decrease the GnRH secretion" addresses amount of the peptide, but leaves the scope of the "influencing of glutamate-receptor controlled cells" undefined.

Further, limitation "for the treatment..." in dependent claims is an intended use limitation which, again, but leaves the scope of the "influencing glutamate-receptor controlled cells" indefinite.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 32 introduces new matter as it addresses subcutaneous administration which is not disclosed in the application as filed.

Claim Rejections - 35 USC § 102.

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 14-17,19-23,25-27 are rejected under 35 U.S.C. 102(b) as anticipated by Sara et al. (Biochim. Biophys. Res. Commun., 165, 766-771, 1989) as evidenced by Yu et al (General and Comparative Endocrinology, 1991, 81, 256-267), or, in the alternative, under 35 U.S.C. 103(a) as unpatentable over Sara et al. (Biochim. Biophys.

Res. Commun., 165, 766-771, 1989) in view of Yu et al (General and Comparative Endocrinology, 1991, 81, 256-267)

The instant claims are directed to method for influencing glutamate-receptor controlled cells by administering peptide Gly-Pro-Glu (GPE) in the amount sufficient to decrease secretion of gonadotropin releasing hormone in the amount sufficient to decrease the GnRH secretion.

Sara teaches effect of peptide Gly-Pro-Glu (GPE) on rat brain cells (i.e., glutamate-receptor controlled cells). Administering GPE results in inhibition of glutamate binding (p. 768) and stimulating, via different mechanisms, release of dopamine and acetylcholine. Thus, the reference teaches influencing glutamate-receptor controlled cells by administering peptide Gly-Pro-Glu (GPE) . With respect to the amount of GPE, although it is addressed in the instant claims as "amount sufficient to decrease the GnRH secretion" the actual amount is not specified. The amounts of PGE in Sara are in the range of 10^{-3} to 10^{-12}M (see figures 1,2) which encompasses the amount used in the instant method – for example, the range 10^{-3} to 10^{-12}M overlaps with to IC_{50} of the range 10^{-8} to 10^{-13} disclosed in the instant method (p. 8, line 3-4). Alternatively, the range 10^{-3} to 10^{-12}M in the reference is equivalent to 0.0035 – 350 mg which overlaps with the range described on p. 3, lines 15-17: 0.1mkg/ -1 mg/ kg body[1] or with the amount of 0.004mg/kg body .

[1] The molecular weight of GPE is 350, the weight of a rat is assumed to be 0.5 kg.

Although Sara reference does not teach that the amounts of GPE as being capable to sufficient to decrease the GnRH secretion it is not possible to distinguish the referenced and claimed method because both have the same steps, administering peptide GPE to influence glutamate-receptor controlled cells in the amount that is believed to be the same. The latter is because the range of amount of GPE peptide in the reference encompasses the amounts used in the instant method.

As for applicant's argument that Sara describes agonistic effect of GPE as compared to antagonistic effect addressed in the instant method, first, the instant claims are not directed to agonistic or antagonistic effect; rather, the claims are directed to influencing glutamate-receptor controlled cells. Second, "agonistic" effect of GPE in the reference and "antagonistic" effect in the instant method are classified so based on observations on effect of GPE on different types of cell secretion. Both experimental conditions (K^+ evoked depolarization in Sara, and Ca^{2+} influx in the instant method) and the effects measured (dopamine or acetylcholine secretion in Sara, and GnRH secretion in the instant method in the instant method) are different and can not be translated one into another. In addition, it is known that the effect observed in Sara, namely dopamine release, causes the effect observed in the instant method, reduction of GnRH release. See, for example Yu et al (General and Comparative Endocrinology, 1991, 81, 256-267) teaches that dopamine inhibits release of GnRH from hypothalamic regions; see abstract. [2]

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[2] Similarly, Koike et al. (Database Medline AN 94152211. Acta endocrinologica,1993, Vol. 129, p. 548-53) teaches inhibitory effect of dopamine on GnRH release in rat hypothalamic cells.

In regard to claims 23,27,29,30 the language "for treatment" is directed to intended use limitations which do not have patentable weight.

Alternatively, with respect to claims 23,25,27,29-33, given the knowledge that GPE peptide stimulates dopamine release which in turn inhibits GnRH release one skilled in the art would be motivated to administer the peptide to patients in need of reducing GnRH release. As for selecting appropriate pharmacological conditions, such as methods of delivery, dosages, etc, such selection of result-oriented variables would be a result of a routine optimization.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 14-17,19-23,25-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U. S. Patent No.5,804,550. The claims of '550 are directed to methods of effecting of glutamate-receptor-controlled cells by peptides, such as GPE (claims 6, 8); in particular the effecting the cells comprises inhibition of GnRH secretion (claim 7). the peptides can be administered systemically or locally (claims 9,10)

Since applicants have not responded to this rejection it is believed that applicants acquiescing therewith.

Conclusion.

8. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

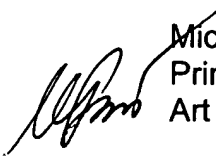
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb